DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 2939684

July 25, 2000

Richard C. Iest, Owner
Richard Iest Dairy
14576 Avenue 14
Madera, California 93637

WARNING LETTER

Dear Mr. Iest:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on June 1 and 2, 2000, by Food and Drug Administration (FDA) Investigator John A. Gonzalez have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On March 29, 2000, you consigned a dairy cow (identified by USDA laboratory report number 331753) to be slaughtered for human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this cow revealed the presence of sulfadimethoxine in the liver at 0.75 parts per million (ppm), and in the muscle at 0.57 ppm. Presently, the tolerance level for sulfadimethoxine in the uncooked edible tissues of cattle is 0.10 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling.

4. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

Your actions have caused the drug Sulfadimethoxine Injection 40% that you use to treat your dairy cows to be adulterated under Section 501(a)(5) of the Act, in that it is a new animal drug within the meaning of Section 201(v), and is unsafe within the meaning of Section 512(a)(1)(B) of the Act, since it is not being used in conformance with approved labeling. Labeling directions specify an intravenous route of administration only. Your practice of administering this product in the muscle is likely the cause of the illegal residues found in the animal you sold for food use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering animals for sale for human food use, which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of June 5, 1989, through March 30, 2000, your firm sold eight cows which were found to contain illegal residues of penicillin and sulfadimethoxine. During the same period, you offered one cow and two calves which were found by USDA to be STOP+ and CAST+, respectively, because of the possible presence of antibiotics. USDA has sent you a letter for each instance in which their analysis found violative levels of drug residues.

Within fifteen (15) days of the receipt of this letter, please notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Suzanne Schenck, Compliance Officer.

Sincerely yours,

Darrell T. Lee
Acting District Director
San Francisco District

cc: [redacted]